

REMARKS

Further and favorable reconsideration is respectfully requested in view of the foregoing amendments and following remarks.

Claim Amendments

Claim 2 has been amended to incorporate the limitations of claim 1, as a result of which claims 1, 3, 4 and 11 have been cancelled, without prejudice.

New claims 15 and 16 have been added to the application. Support for these claims is found on page 5, lines 21-22, as well as Embodiments 2, 3 and 4 on pages 10-12 of Applicants' specification.

The claims have also been amended to make editorial changes, in order to better comply with U.S. practice.

No new matter has been added to the application by these amendments.

Patentability Arguments

The patentability of the present invention over the disclosures of the references relied upon by the Examiner in rejecting the claims, will be apparent upon consideration of the following remarks.

Discussion Regarding Applicants' Invention

Applicants' claims recite a processed cheese having angiotensin converting enzyme inhibitory activity of 350 units/gram or more, wherein the processed cheese is obtained by processing a raw material comprising natural cheese having angiotensin converting enzyme inhibitory activity of 420 units/gram or more. [Claim 2] Additionally, Applicants claim a method of producing said processed cheese. [Claim 5]

Applicants' claimed invention has the following advantages:

- (1) Consumption of 10 to 15 grams/day of Applicants' processed cheese results in

intake of total angiotensin converting enzyme (ACE)-inhibitory activity of 5000 units. This is considered to be effective in sustaining a normal blood pressure.

The average amount of cheese consumed by a Japanese person is about 5.5 grams/day. It has been determined, for the first time, that the ACE-inhibitory activity of currently marketed processed cheese is, at most, around 200 units/gram. (Please see Table 1 on page 2 of Applicants' specification.) Thus, in order to reach the ACE-inhibitory activity which would sustain a normal blood pressure (as discussed above), 25 grams/day of currently marketed processed cheese must be consumed. This is clearly much higher than the average amount of cheese consumed by a Japanese person in a day. Thus, it would be difficult for a Japanese person to seek a sustained blood pressure by consumption of a currently marketed processed cheese.

Applicants' invention provides a processed cheese with ACE-inhibitory activity of 350 units/gram or more. Accordingly, 5000 units of total ACE-inhibitory activity (the amount considered effective in sustaining a normal blood pressure) may be obtained by consuming around 10 to 15 grams of processed cheese per day.

(2) Applicants' processed cheese may be uniformly commercialized.

It is known that natural cheese has ACE-inhibitory activity, as indicated in the reference relied upon by the Examiner. However, it is very difficult to stably produce a natural cheese with constant ACE-inhibitory activity on a large scale, because the ACE-inhibitory activity varies depending on factors such as its ripening degree, the mold used, and ripening step. Additionally, it is also difficult to provide the market with a natural cheese with constant ACE-inhibitory activity, because ACE-inhibitory activity changes during distribution.

On the other hand, Applicants have created a processed cheese with a desired ACE-inhibitory activity by selecting at least one type of natural cheese, as a raw material, based on its measured ACE-inhibitory activity. Since processed cheese is heat-treated during production, the ACE-inhibitory activity does not change during circulating process. Accordingly, a processed cheese having a constant amount of ACE-inhibitory activity may be uniformly provided.

Additional embodiments of Applicants' invention involve a methods of manufacturing a processed cheese by measuring the ACE-inhibitory activity of a natural cheese in advance, and then mixing two natural cheeses, both having high ACE-inhibitory activity (420 units/gram or more), or mixing a natural cheese having high ACE-inhibitory activity (420 units/gram or more) with a natural cheese having low ACE-inhibitory activity (less than 420 units/gram). [Please see new claims 15 and 16.]

Rejections Under 35 U.S.C. § 102(b)

Draaisma et al. (US 2002/0182301)

The rejection of claims 1 and 2 under 35 U.S.C. § 102(b) as being anticipated by Draaisma et al. (US 2002/0182301) is respectfully traversed.

The Position of the Examiner

The Examiner takes the position that Draaisma et al. disclose a fermented milk product having angiotensin converting enzyme I (ACE) inhibitory activity. The Examiner states that the milk product is produced from milk fermented with *Lactobacillus delbrueckii subsp. lactis*. The Examiner states that since the reference discloses ACE inhibitory activity of at least 35 U/ml, it is clear that the amount disclosed by the reference overlaps Applicants' recited amount.

Applicants' Arguments

Applicants respectfully disagree with the Examiner's position for the following reasons.

Draaisma et al. disclose a cheese as an example of a fermented dairy product having an ACE-inhibitory effect of at least 35%. The Examiner states that "it is clear that the amount disclosed by [the reference] overlaps that presently claimed." However, Applicants respectfully disagree.

First, the Examiner has provided no evidence to support the assertion that this description overlaps Applicants' recited range. It cannot be considered or presumed that a cheese having ACE-inhibitory activity of 350 units/gram or more is described, as required by Applicants'

claims.

Second, the reference fails to specifically show how to obtain a cheese which possesses an ACE-inhibitory effect of at least 35%. Draaisma et al. have found a lactobacillus with high ACE-inhibitory activity, Lb.05-14 strain (CBS 109295 strain), and only disclose a yogurt as fermented milk using the lactobacilli. The reference describes that skimmed milk was fermented with a wide variety of lactobacilli before ACE-inhibitory activity in the obtained whey was measured ([0069]), and it only shows a yogurt produced using Lb.05-14 strain as a specific product. Thus, Draaisma et al. never disclose the ACE-inhibitory activity of the portion from which whey was excluded, and from which cheese is obtained.

On the contrary, the natural cheese used as a raw material in Applicants' invention is obtained from a portion from which whey was excluded, and is thus totally different from the fermented milk (whey) of Draaisma et al., which is discarded during production of natural cheese. [Natural cheese is a product obtained by eliminating whey from lactobacillus-fermented raw milk. This is known to those of ordinary skill in this art.]

Third, it is unclear what is meant by "a fermented dairy product having an ACE-inhibitory effect of at least 35%." As disclosed in paragraphs [0063] to [0067] of the reference, the ACE-inhibitory activity in Draaisma et al. means a decreased ACE activity value obtained by comparison of ACE activity value in presence of an ACE-inhibitory substance with the ACE activity value in absence of an ACE-inhibitory substance. For example, it can be considered that the reference means that 35% of ACE activity of a fermented dairy product which originally had ACE activity of 100 units/gram was suppressed, to create a food having 65% of ACE activity. This is totally different from Applicants' claimed processed cheese, which requires ACE-inhibitory activity of 350 units/gram or more.

Additionally, it can be considered that when the fermented dairy product described in Draaisma et al. is added to a food having ACE activity of 100 units/gram, 35% of ACE activity is suppressed, resulting in a food having an ACE activity of 65 units/gram. Since only 35% of ACE activity has to be suppressed, it does not matter what amount of the fermented dairy product is used. 35% of ACE activity may be suppressed using 1 gram of fermented dairy product, or 35% of ACE activity may be suppressed using 10 gram of fermented dairy product.

Therefore, contrary to the Examiner's assertion, the reference clearly fails to describe a processed cheese having ACE-inhibitory activity of 350 units/gram or more, as required by Applicants' claims. Additionally, the cited reference fails to teach or suggest a processed cheese having ACE-inhibitory activity of 350 units/gram or more, wherein the processed cheese is obtained by processing a raw material comprising natural cheese having ACE-inhibitory activity of 420 units/gram or more.

Accordingly, the cited reference fails to teach each and every limitation of Applicants' recited claims. Thus, Applicants respectfully request that the above-rejection be withdrawn.

Henson (WO 97/18718)

The rejection of claims 1-14 under 35 U.S.C. § 102(b) as being anticipated by Henson (WO 97/18718) is respectfully traversed.

The Position of the Examiner

The Examiner takes the position that Henson et al. disclose a method for producing a reduced sodium processed cheese from a natural cheese.

Applicants' Arguments

Applicants respectfully disagree with the Examiner's position for the following reasons.

Henson only describes processed cheese with decreased sodium and potassium. The cited reference fails to describe a processed cheese having ACE-inhibitory activity of 350 units/gram or more, wherein the processed cheese is obtained by processing a raw material comprising natural cheese having ACE-inhibitory activity of 420 units/gram or more, as required by Applicants' claims.

The Examiner states that since the reference discloses processing natural cheese, it is clear that the natural cheese would inherently have ACE inhibitory activity of 420 units/gram or more. However, the Examiner has provided no evidence to support this assertion.

As described in Applicants' specification, the inventors have revealed that ACE-inhibitory activities of natural cheeses are different depending on aging terms, production

methods, etc., even when measuring the same cheddar cheese. Thus, even if the aging terms and the production methods of the natural cheeses described in the cited reference are stated, the ACE-inhibitory activities of these natural cheeses, and the ACE-inhibitory activities of the processed cheeses produced with these cheeses, are not presumable based on this information. Thus, it can not be determined whether ACE-inhibitory activity of the obtained processed cheese is 350 units/g or more, or whether ACE-inhibitory activity of the natural cheese used as a raw material is 420 units/g or more. The Examiner's conclusions are merely presumptions, which lack supporting evidence.

As described above, Applicants' invention is based on the understanding that natural cheeses have different ACE-inhibitory activities, depending on aging terms or production methods. Applicants' invention is based on the discovery to select, from among such various natural cheeses having different ACE inhibition activities, a natural cheese having ACE-inhibitory activity of 420 units/g or more, to produce a processed cheese having an ACE-inhibitory activity of 350 units/g or more.

Thus, the reference fails to teach each and every limitation of Applicants' claims. Accordingly, Applicants respectfully request that the above-rejection be withdrawn.

JP 2003-033136 (Machine translation)

The rejection of claims 1-14 under 35 U.S.C. § 102(b) as being anticipated by JP 2003-033136 (Machine translation) is respectfully traversed.

The Position of the Examiner

The Examiner takes the position that JP '136 discloses a processed cheese with a sodium content of 800 mg/100 g or less and had a potassium content of 100 mg/100 g or more.

Applicants' Arguments

Applicants respectfully disagree with the Examiner's position for the following reasons.

JP '136 only describes process cheese with decreased sodium and potassium. The reference fails to describe a processed cheese having ACE-inhibitory activity of 350 units/gram

or more, wherein the processed cheese is obtained by processing a raw material comprising natural cheese having ACE-inhibitory activity of 420 units/gram or more, as required by Applicants' claims.

The Examiner states that since the reference discloses processing natural cheese, and discloses New Zealand cheddar, it is clear that the natural cheese would inherently have ACE inhibitory activity of 420 units/gram or more. However, the Examiner has provided no evidence to support this assertion.

As discussed above regarding WO '718, ACE-inhibitory activities of natural cheeses are different depending on aging terms, production methods, etc. Accordingly, the Examiner's presumption that the cheeses of the reference will meet Applicants' claims is unsupported and untenable.

Thus, the reference fails to teach each and every limitation of Applicants' claims. Accordingly, Applicants respectfully request that the above-rejection be withdrawn.

Conclusion

Therefore, in view of the foregoing amendments and remarks, it is submitted that each of the grounds of rejection set forth by the Examiner has been overcome, and that the application is in condition for allowance. Such allowance is solicited.

If, after reviewing this Amendment, the Examiner feels there are any issues remaining which must be resolved before the application can be passed to issue, the Examiner is respectfully requested to contact the undersigned by telephone in order to resolve such issues.

Respectfully submitted,

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